K031876

NOV 21 2003

EXHIBIT 2
510(k) Summary of Safety and Effectiveness

MED SYSTEMS
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Phone 800.345.9061
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June 9, 2003
Contact: Jim Davis, President

1. Identification of the Device:
   Proprietary-Trade Name: Med Systems Electro Flo Percussor Model 5000
   Classification Name: Powered Chest Percussor Product Code BYI
   Common/Usual Name: Powered Chest Percussor

2. Equivalent legally marketed devices: This product is similar in function to the Model 2500 "Fluid Flo" percussor that our company has manufactured for hospitals since 10-23-82 under 510(k) number K802399. (Company formerly known as Medical Equipment Development Co., Inc.) as well as PURITAN BENNETT McSHIRLEY K801982 and SOUTHWEST MEDICAL MFG. INC (STROM) K821265, K821570 K813438

3. Indications for Use (intended use) : The intended use of the Med Systems Electro Flo Percussor Model 5000 is provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. Indications for this form of therapy are described by the American Association for Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy [(1)] (1991). According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the Med Systems Electro Flo Percussor Model 5000is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for purposes of collecting mucus for diagnostic evaluation.
   (1). Bronchial Hygiene Guidelines Committee, American Association for Respiratory Care. AARC Clinical Practice Guideline: Postural Drainage Therapy. Respiratory Care 1991; 36: 1418 - 1426

4. Description of the Device:. The Model 5000 "Electro Flo" Percussor is just an electrically cycled hammer. It has the exact same function and operation as the Model 2500 "Fluid Flo" percussor that our company has manufactured for hospitals since 10-23-82 under 510(k) number K802399. The "Fluid Flo" percussor is cycled by an oscillating pneumatic valve whereas the "Electro Flo" percussor is cycled electronically.

5. Substantial Equivalence Chart

Feature	**Med Systems 2500 Fluid Flo K802399**	**PURITAN BENNETT McSHIRLEY K801982**	**SOUTHWEST MEDICAL MFG. INC STROM K821265, K821570 K813438**	**Med Systems 5000 Electro Flo (This submission)**
INDICATION For USE	For respiratory secretion clearance for COPD, cystic fibrosis, emphysema, atelectasis and other obstructive lung conditions	SAME	SAME	SAME
Power and Control	Pneumatic Solenoid	Electric Solenoid	Electric Motor	Electronic Solenoid
Speed	5 to 15 Hz	6 to 60 Hz	5 to 60 Hz	5 to 25 Hz
Weight	1.5 pounds	3 pounds	5 pounds	1.5 pounds
Energy source	Pneumatic	120 v 60 Hz AC	120 v 60 Hz AC	120 v 60 Hz AC

6. Conclusion

After analyzing bench and electrical safety testing data, it is the conclusion of MED Systems that the Med Systems Electro Flo Percussor Model 5000 is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2003

MED Systems
C/O Mr. Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K031876
Trade/Device Name: Electro Flo Percussor, Model 5000
Regulation Number: 21 CFR 868.5665
Regulation Name: Percussor, Powered-Electric
Regulation Class: II
Product Code: BYI
Dated: August 20, 2003
Received: August 25, 2003

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

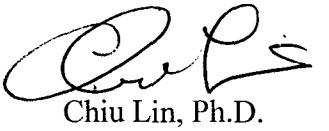
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K031876

Device Name: Med Systems Electro Flo Percussor Model 5000

Indications for Use:
The intended use of the Med Systems Electro Flo Percussor Model 5000 is the same as the predicate device, which is to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. Indications for this form of therapy are described by the American Association for Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy [(1)] (1991). According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the Med Systems Electro Flo Percussor Model 5000 is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for purposes of collecting mucus for diagnostic evaluation.

(1). Bronchial Hygiene Guidelines Committee, American Association for Respiratory Care. AARC clinical practice guideline: postural drainage therapy. Respiratory Care 1991; 36: 1418 - 1426.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over the Counter Use**_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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